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DUDASH, D	

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DATE MAILED: 11/17/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 8/14/95 ☑ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 9-19 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☒ Claims 1-8 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 9-19 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☒ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☒ been received ☐ not been received ☒ been filed in parent application, serial no. 08/173542; filed on 12/22/93.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Part III DETAILED ACTION

Specification

1. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does not provide support for the invention as is now claimed.

The specification lacks support for "an at least partially radially contracted stent", "an at least partially expanded stent", or "evaporating at least a portion of the solvent" as in new claims 15-19. The specification also lacks support for "bonding" as in instant claims 12 and 17.

Claim Rejections - 35 USC § 112

2. Claims 12 and 15-19 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

3. Claims 9-14 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point

out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is vague and indefinite due to lack of sequential language, especially in view of the evaporating and polymerizing steps, as the evaporating step is recited before polymerizing, but the polymerizing step requires that the elastomeric composition be dissolved in a solvent. Claim 11 is similarly vague and indefinite. Further, claim 9, lines 16 and 20, is confusing and indefinite due to "a solvent", because "a solvent" is already recited in line 13. If the same solvent is intended then the claim should read "the solvent" or "said solvent". Claim 9 is further vague and indefinite due to "a portion", lines 9 and 10, because a portion of the sent is already recited in line 6. Claims 10-14 are confusing and indefinite for analogous reasons. Claim 10 is indefinite and confusing because claim 9 requires coating the tube and stent with the elastomeric composition in a solvent, while claim 10 requires evaporation of the solvent before coating of the stent, which is inconsistent, The stent cannot be coated with a composition in a solvent if the solvent is not there. Claim 14 is further confusing and indefinite due to "an elastomeric composition dissolved in a solvent" and "an elastomeric polymerisable composition dissolved in solvent", which also renders line 17 vague and indefinite due to lack of clear antecedent basis for "the solvent".

Claims 15 and 16 are confusing and incorrect due to "an elastomeric polymerisable composition comprising a solvent".

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 12 and 17 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by MacGregor.

MacGregor teaches that in one method of deploying, stents are compressed circumferentially so that it may be fitted within a tubular body, such as a catheter, and subsequently the stent is expanded within the catheter (col. 1, line 65-col.2, line 50). The disclosure of catheters inherently meets the limitation of a tube made of an elastomer. See: Fig.2; col.5, line 8-col.6, line 43.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in

> section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

7. Claims 13,14,18 and 19 are rejected under 35 U.S.C. § 103 as being unpatentable over MacGregor '253 taken with Gianturco '824 and further in view of Crocker *et al*.

MacGregor teaches that in one method of deploying, stents are compressed circumferentially so that it may be fitted within a tubular body, such as a catheter, and subsequently the stent is expanded within the catheter (col. 1, line 65-col.2, line 50). The disclosure of catheters inherently meets the limitation of a tube made of an elastomer. See: Fig.2; col.5, line 8-col.6, line 43. MacGregor further teaches use of biocompatible and hemocompatible adhesives in manufacturing the stents, and further teach enhancing the stent by coating the exterior surface of the stent.

Gianturco relates to stents for reducing restenosis wherein the stents are attached to a flexible sleeve such that the gaps defined by the stent are substantially covered(col.1, lines 13-56). Gianturco teaches that stents may be attached to the outer sleeves by various methods including stitching, gluing or embedding, thus meeting the adhesives of the instant claims 13 and 18(col.2, lines 56-65; col.3, lines 10-57). He lacks applying the adhesive or embedding composition to the inner surface of the sleeve, though logically it is the only way to uniformly apply a coating between the stent and a tubular sleeve. If the stent itself were precoated in either the expanded or contracted state, one would expect either bare spots or uneven coating due to the required further contraction and/or expansion in placing the stent into the sleeve.

Crocker *et al.* teach adhesive bonding of delivery balloons to catheter bodies. They teach catheters supported wholly or in part by stents of various structures, such as spring coil or braided or woven polymer or metal filaments. The spring coil is preferably provided with an outer sheath or coating. The neck portion of the balloon catheter is secured to the stent by adhesives, thermal bonding or shrinking. They further teach filling the space between the tubular body wall and stent with adhesive to provide a fluid tight seal, suggesting the method of the instant claims. See: col.3, lines 43-53; col.4, line 55-

col.6, line 50; col.7, lines 19-30; col.10, lines 27-32; col.13, lines 4-28; col.14, lines 52-65; col. 15, lines 20-39.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the process of MacGregor by use of adhesive to join the stent and sleeve, as taught by Gianturco, and further to have applied the adhesive to the interior of a polymeric outer tube, as suggested by the teachings of Crocker *et al.*, because of the expectation of uniformly adhering the stent to a flexible covering layer.

8. Claims 11 and 16 are rejected under 35 U.S.C. § 103 as being unpatentable over Crocker et al. as applied to claims 13,14,18 and 19 above and further in view of Kiezulas.

Crocker, as discussed above, teaches stents which are preferably provided with an outer sheath or coating, which may be applied by dipping, spraying, heat shrinking or extrusion(col.6, lines 14-25).

Kiezulas teaches coating medical apparatus, including catheters, guidewires, stylets and introducers, with cross-linkable polymeric compositions in order to provide abrasion resistance and lubricity, thus protecting the substrate. The coating may be applied using a variety of methods, preferred methods being dipping, spraying, rolling and brushing, followed by curing of the coating. She exemplifies coating a catheter-mounted balloon wherein the balloon is preferably inflated prior

to coating, which "allows the formation of a coating layer having a generally uniform thickness and also prevents adhesion between balloon surfaces that may contact one another in the deflated state". See: col.1, lines 7-38; col.2 lines 11-40; col.3, lines 7-54; col.4, lines 48-68. Kiezulas further teaches use of a urethane dispersion in a solution of solvents, suggesting the use of polymeric solution.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the process of Crocker et al. by substituting known methods of coating medical apparatus by known equivalent methods, such as the rolling as taught by Kiezulas, because of the expectation of successfully applying coating only to the outside of the stent without the problem of overspray, for example. Further, one would have been logically motivated to use an easily cleanable substrate as the rolling surface because of the expectation of using it for coating multiple devices.

Allowable Subject Matter

9. Claims 9 and 15 would be allowable if rewritten or amended to overcome the rejection under 35 U.S.C. 112.

10. Claim 10 would be allowable if rewritten to overcome the rejection under 35 U.S.C. 112 and to include all of the limitations of the base claim and any intervening claims.

Response to Amendment

11. Applicant's arguments with respect to claims 11-14,16-19,9,10,15 have been considered but are deemed to be moot in view of the new grounds of rejection.

Conclusion

12. Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Dudash whose telephone number is (703) 308-2328.

dld
November 13, 1995

DIANA DUDASH
PRIMARY EXAMINER
GROUP 1100